DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Synthes (USA) Products LLC
Ms. Susan Lewandowski
Project Leader, Regulatory Affairs – CMF
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K141241
Trade/Device Name: MatrixRIB Endo Thoracoscopic Rib Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: May 12, 2014
Received: May 13, 2014

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4.0 Indications for Use Statement

510(k) Number (if known): K141241

Device Name:

MatrixRIB Endo Thoracoscopic Rib Plating System

Indications for Use:

The MatrixRIB Endo Thoracoscopic Rib Plating System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Prescription Use **X** (Per 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

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5.0 510(k) Summary

Date Prepared: May 12, 2014

Submitter: Synthes (USA) Products LLC
1302 Wrights Lane East
West Chester, PA 19380
United States of America

Contact: Susan Lewandowski
Lewandowski.susan@synthes.com
Telephone 610-719-5852
Facsimile 484-356-9682

Device Name: MatrixRIB Endo Thoracoscopic Rib Plating System

Device Classification Information:

Product Code	Device Name	Device Class	Regulation Number	Regulation Description
HRS	Plate, Fixation, Bone	2	21 CFR 888.3030	Single, multiple component metallic bone fixation appliances and accessories

The MatrixRIB Endo Thoracoscopic Rib Plating System contains Class 2 implants as well as Class 1 instruments and accessories.

Predicate Devices:

- Synthes MatrixRIB Fixation System (K081623)
- Acute Innovations Modular RibLoc System (K113318)
- Synthes Sternal Fixation System (K112689)

Indications for Use:
The MatrixRIB Endo Thoracoscopic Rib Plating System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

Device Description:
The MatrixRIB Endo Thoracoscopic Rib Plating System consists of a pre-assembled stability plate with threaded locking posts, and locking caps intended for the minimally invasive thoracoscopic fixation and stabilization of ribs. The implants are manufactured from titanium (CPTi4) and titanium alloy (Ti-6Al-7Nb).

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Comparison to Predicate Devices:

Indications
The MatrixRIB Endo Thoracoscopic Rib Plating System has the same general Indications for Use as the predicate devices.

Technological Similarities of MatrixRIB Endo Thoracoscopic Rib Plating System to Predicates

- Same general principle of operation for all components; provide fixation and stabilization to rib fractures so that fusion may occur.
- Both MatrixRIB Endo and RibLoc Systems rely on strong mechanical fixation that lags the plate to the rib.
- All Systems are used with smaller incisions allowing a less invasive (RibLoc) or minimally invasive (MatrixRIB splint, MatrixRIB Endo) surgical technique to provide access to the fracture and implantation of internal fixation.
- For all Systems, same or similar materials used for construction of fixation devices e.g. Titanium and/or Titanium Alloy
- The MatrixRIB Endo stability plate lengths are within those of the predicates
- All Systems are designed to accommodate the anatomy of the rib
- MatrixRIB Endo and RibLoc Systems both have plates that can be contoured both external to the patient and intraoperatively.
- Both MatrixRIB Endo and MatrixRIB (splint) are designed to be used without removing periosteum in order to maximize blood supply to the bone.
- Both the MatrixRIB Endo and RibLoc Systems “sandwich” the rib; the MatrixRIB Endo, the rib lies between the stability plate placed posteriorly and the locking caps placed anteriorly and the RibLoc, the rib lies between the plate which is placed anteriorly and supports with anterior, superior, and posterior rib surfaces due to its u-shaped channel supports.

Technological Differences of MatrixRIB Endo

- Stability Plates are pre-assembled with threaded locking posts that can pivot about the plate slot to accommodate both the surgical technique and the final implantation
- Prior to fixation with the threaded locking caps, threaded locking post slides freely along the plate slot to accommodate intraoperative positioning.
- Locking caps are sized to accommodate a variety of rib thicknesses
- MatrixRIB Endo uses a standard thoracoscopic approach with anterior stab incisions; RibLoc uses a standard thoracoscopic approach with large incision over rib fracture
- MatrixRIB splints are placed into the intramedullary canal of the rib, while the MatrixRIB Endo “sandwiches” the rib; the rib lies between the stability plate placed posteriorly and the locking caps placed anteriorly.

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Non-clinical performance data:
Non-clinical testing and analyses comparing the proposed devices to the predicates within this submission include:

- Biomechanical Cadaveric Testing
- Static Compression Bending
- Dynamic Compression Bending

The non-clinical performance data demonstrate that the mechanical performance of the proposed MatrixRIB Endo Thoracoscopic Rib Plating System is comparable to that of the predicates.

Clinical performance data:
Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence:
The proposed devices have the same intended use as the predicate devices. The mechanical testing included in this submission demonstrates that:

- Any differences in technological characteristics of the predicates do not raise any new questions of safety and effectiveness.
- The proposed devices are at least as safe and effective as the predicates.

It is concluded that the information included in this submission supports substantial equivalence.

(End of summary)